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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,415	03/20/2006	Dharmaraj Ramachandra Rao	8693.009.US0000	2363
77176	7590	11/18/2008		
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EXAMINER				
CHU, YONG LIANG				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
11/18/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/539,415

**Applicant(s)**

RAO ET AL.

**Examiner**

YONG CHU

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CI/CC)  
Paper No(s)/Mail Date 08/04/2008
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

Claims 1-6, and 18-22 are pending in the instant application. Claims 18-22 remain withdrawn as non-elected subject matter. Therefore, claims 1-6 are under examination on the merits.

### ***Information Disclosure Statement***

Applicants' Information Disclosure Statement, filed 08/04/2008 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

### ***Response to Amendments/Arguments***

The Amendments by Applicants' representative Thomas P. Pavelko dated on 08/04/2008 has been entered.

### **Rejection of claims under 35 U.S.C. §102(b)**

Applicant's argument over rejection of claims 1 and 2 on the ground that Column 5, lines 46-55 do not teach the chiral acids specified in claims 1-2 has been considered, but is not persuasive. As cited in the previous Office action, the '388 patent teaches the preparation of the active isomer by resolving the racemic mixture, and useful resolving agents include dibenzoyl-d- and -l-tartaric acid, lines 46-55, Column 5. Dibenzoyl-d- and -l-tartaric acid are chiral acid and claimed in claim 2 of the instant application, see page 4 lines 1-2 of the previous Office action. The term "substantially free of (-) duloxetine" does not carry patentable weight because the limiting steps of the preparation procedure in the '388 patent are the same as instantly claimed steps, and the resulting product from the prior art is (+)duloxetine as Example 14 showing active

optical rotation as  $[\alpha]_{589}^{25} = +82^\circ$  and  $[\alpha]_{365}^{25} = +391^\circ$ . There is no reason to believe that prior art compound is not optically pure. Therefore, the rejection is maintained.

**Rejection of claims under 35 U.S.C. §103(a)**

Applicant's arguments over rejection of claims 1-6 on the ground that Column 5, lines 46-55 do not teach the chiral acids specified in the claims, and the rejection is based on hindsight reconstruction have been considered, and are found not persuasive. As cited in the previous Office action, the '388 patent teaches the preparation of the active isomer by resolving the racemic mixture, and useful resolving agents include dibenzoyl-d- and -l-tartaric acid, lines 46-55, Column 5. Dibenzoyl-d- and -l-tartaric acid are chiral acid and claimed in claim 2 of the instant application, see page 4 lines 1-2 of the previous Office action. The term "substantially free of (-) duloxetine" does not carry patentable weight because the limiting steps of the preparation procedure in the '388 patent are the same as instantly claimed steps, and the resulting product from the prior art is (+)duloxetine as Example 14 showing active optical rotation as  $[\alpha]_{589}^{25} = +82^\circ$  and  $[\alpha]_{365}^{25} = +391^\circ$ . There is no reason to believe that prior art compound is not optically pure. The cited '806 patent and Wheeler references teach the additional resolving chiral acids and duloxetine hydrochloride salt for the additional limitations in claims 3-6. Converting (-)duloxetine obtained from step (i) to (+)duloxetine is a common practice to one of skills in the art to re-cycling the material as cost saving motivation. The combined cited references and the common sense render the instant claims 1-6 obvious. Therefore, the rejection is maintained.

***Conclusions***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone

Art Unit: 1626

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu/  
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Art Unit 1626

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